AMENDMENTS TO THE CLAIMS

1.–26. (Cancelled)

27. (Currently Amended) An oral solid dose rapidly disintegrating nanoparticulate active agent formulation comprising:

(a) a solid dose matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and

(b) within the solid dose matrix a nanoparticulate active agent composition comprising:

(i) a poorly soluble active agent having an effective average particle size of less than about 2000 nm prior to inclusion in the dosage form; and

(ii) at least one surface stabilizer adsorbed on the surface thereof;

wherein the active agent is selected from the group consisting of analgesics, ~~anti-inflammatory agents,~~ anthelmintics, anti-arrhythmic agents, ~~antibiotics,~~ anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immuriological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines;

~~wherein the active agent is not a non-steroidal anti-inflammatory drug;~~ and

wherein the solid dose matrix surrounding the nanoparticulate active agent and at least one surface stabilizer disintegrates or dissolves upon contact with saliva in less than about 3 minutes.

28. (Previously Presented) The composition of claim 27, wherein the solid dose matrix disintegrates or dissolves upon contact with saliva in a time period selected from the group consisting of less than about 2 minutes, less than about 90 seconds, less than about 60 seconds, less than about 45 seconds, less than about 30 seconds, less than about 20 seconds, less than about 15 seconds, less than about 10 seconds, and less than about 5 seconds.

29. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 1500 nm.

30. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 1000 nm.

31. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 600 nm.

32. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 400 nm.

33. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 300 nm.

34. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 250 nm.

35. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 100 nm.

36. (Previously Presented) The composition of claim 27, wherein the effective average particle size of the active agent particles is less than about 50 nm.

37. (Previously Presented) The composition of claim 27, wherein the concentration of the active agent is from about 0.1% to about 99.9% (w/w).

38. (Previously Presented) The composition of claim 37, wherein the concentration of the active agent is from about 5% to about 70% (w/w).

39. (Previously Presented) The composition of claim 38, wherein the concentration of the active agent is from about 15% to about 40% (w/w).

40. (Previously Presented) The composition of claim 27, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 99.9% to about 0.1% (w/w).

41. (Previously Presented) The composition of claim 40, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 95% to about 30% (w/w).

42. (Previously Presented) The composition of claim 41, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 85% to about 60% (w/w).

43. (Previously Presented) The composition of claim 27, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of a sugar, a sugar alcohol, a starch, a natural gum, a natural polymer, a synthetic derivative of a natural polymer, a synthetic polymer, and mixtures thereof.

44. (Previously Presented) The composition of claim 43, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of lactose, glucose, mannose, mannitol, sorbitol, xylitol, erythritol, lactitol, maltitol, corn starch, potato starch, maize starch, gelatin, carrageenin, acacia, xanthan gum, an

alginate, dextran, maltodextran, polyethylene glycol, polyvinylpyrrolidone, polyvinylalcohol, polyoxyethylene copolymers, polyoxypropylene copolymers, polyethyleneoxide, and a mixture thereof.

45. (Previously Presented) The composition of claim 43, wherein said excipient is selected from the group consisting of a direct compression material and a non-direct compression material.

46. (Previously Presented) The composition of claim 45, wherein said excipient is selected from the group consisting of a spray-dried mannitol and spray-dried lactose.

47. (Previously Presented) The composition of claim 27, wherein the solid dose formulation is made by fluid bed granulation.

48. (Previously Presented) The composition of claim 27 further comprising at least one effervescent agent.

49. (Previously Presented) The composition of claim 27, wherein said composition has been lyophilized.

50. (Previously Presented) The composition of claim 27, wherein the poorly soluble active agent is in the form of crystalline particles, semi-crystalline particles, or amorphous particles.

51.-53. (Cancelled)

54. (Withdrawn) The composition of claim 27, wherein the active agent is nifedipine.

55. (Withdrawn) The composition of claim 27, wherein the active agent is glipizide.

56. (Withdrawn) A method of preparing an oral solid dose rapidly disintegrating nanoparticulate active agent formulation comprising:

(a) combining:

(i) a nanoparticulate active agent composition of a poorly soluble active agent and at least one surface stabilizer, wherein the active agent has an effective average particle size of less than about 2000 nm, and

(ii) at least one pharmaceutically acceptable water-dispersible or water-soluble excipient, which forms a solid dose matrix surrounding the nanoparticulate active agent composition; and

(b) forming a solid dose formulation, wherein the solid dose matrix surrounding the nanoparticulate active agent and surface stabilizer substantially completely disintegrates or dissolves upon contact with saliva in less than about 3 minutes;

wherein the active agent is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immuriological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

57. (Withdrawn) The method of claim 56, wherein the solid dose matrix substantially completely disintegrates or dissolves upon contact with saliva in a time period selected from the group consisting of less than about 2 minutes, less than about 90 seconds, less than about 60 seconds, less than about 45 seconds, less than about 30 seconds, less than about 20 seconds, less than about 15 seconds, less than about 10 seconds, and less than about 5 seconds.

58. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 1500 nm.

59. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 1000 nm.

60. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 600 nm.

61. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 400 nm.

62. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 300 nm.

63. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 250 nm.

64. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 100 nm.

65. (Withdrawn) The method of claim 56, wherein the effective average particle size of the active agent particles is less than about 50 nm.

66. (Withdrawn) The method of claim 56, wherein the nanoparticulate composition and the at least one water-dispersible or pharmaceutically acceptable water-soluble excipient are combined in step (a) using fluid bed granulation to form granules of the nanoparticulate composition and at least one water-soluble or water-dispersible excipient, which are then compressed in step (b) to form a solid dose formulation.

67. (Withdrawn) The method of claim 56, comprising adding additional pharmaceutically acceptable water-soluble or water-dispersible excipient to the granules formed by fluid bed granulation in step (a) prior to compression of the granules in step (b) to form a solid dose formulation.

68. (Withdrawn) The method of claim 56 wherein step (b) comprises compression of the composition formed in step (a).

69. (Withdrawn) The method of claim 56 wherein step (b) comprises lyophilization of the composition formed in step (a).

70. (Withdrawn) The method of claim 56 additionally comprising adding at least one effervescent agent to the composition prior to step (b).

71. (Withdrawn) The method of claim 56, wherein the concentration of the active agent is from about 0.1% to about 99.9% (w/w).

72. (Withdrawn) The method of claim 71, wherein the concentration of the active agent is from about 5% to about 70% (w/w).

73. (Withdrawn) The method of claim 72, wherein the concentration of the active agent is from about 15% to about 40% (w/w).

74. (Withdrawn) The method of claim 56, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 99.9% to about 0.1% (w/w).

75. (Withdrawn) The method of claim 74, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 95% to about 30% (w/w).

76. (Withdrawn) The method of claim 75, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 85% to about 60% (w/w).

77. (Withdrawn) The method of claim 56, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of a sugar, a sugar alcohol, a starch, a natural gum, a natural polymer, a synthetic derivative of a natural polymer, a synthetic polymer, and mixtures thereof.

78. (Withdrawn) The method of claim 77, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of lactose, glucose, mannose, mannitol, sorbitol, xylitol, erythritol, lactitol, maltitol, corn starch, potato starch, maize starch, gelatin, carrageenin, acacia, xanthan gum, an alginate, dextran, maltodextran, polyethylene glycol, polyvinylpyrrolidone, polyvinylalcohol, polyoxyethylene copolymers, polyoxypropylene copolymers, polyethyleneoxide, and a mixture thereof.

79. (Withdrawn) The method of claim 77, wherein said excipient is selected from the group consisting of a direct compression material and a non-direct compression material.

80. (Withdrawn) The method of claim 79, wherein said excipient is selected from the group consisting of a spray-dried mannitol and spray-dried lactose.

81. (Withdrawn) The method of claim 56, wherein the poorly soluble active agent is in the form of crystalline particles, semi-crystalline particles, amorphous particles, or a mixture thereof.

82. (Withdrawn) The method of claim 56, wherein the active agent is a COX-2 inhibitor type non-steroidal anti-inflammatory drug.

83. (Withdrawn) The method of claim 56, wherein the active agent is ketoprofen.

84. (Withdrawn) The method of claim 56, wherein the active agent is naproxen.

85. (Withdrawn) The method of claim 56, wherein the active agent is nifedipine.

86. (Withdrawn) The method of claim 56, wherein the active agent is glipizide.

87. (Previously Presented) A method of treating a mammal comprising administering to the mammal an effective amount of a solid dose rapidly disintegrating nanoparticulate active agent formulation wherein:

(a) the formulation comprises a solid dose matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and

(b) within the solid dose matrix a nanoparticulate active agent composition comprising:

(i) a poorly soluble active agent having an effective average particle size of less than about 2000 nm prior to inclusion in the dosage form; and

(ii) at least one surface stabilizer;

wherein the active agent is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines;

wherein the active agent is not a non-steroidal anti-inflammatory drug; and

wherein the solid dose matrix surrounding the nanoparticulate active agent and surface stabilizer disintegrates or dissolves upon contact with saliva in less than about 3 minutes.

88. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 1500 nm.

89. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 1000 nm.

90. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 600 nm.

91. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 400 nm.

92. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 300 nm.

93. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 250 nm.

94. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 100 nm.

95. (Previously Presented) The method of claim 87, wherein the effective average particle size of the active agent particles is less than about 50 nm.

96. (Previously Presented) The method of claim 87, wherein the concentration of the active agent is from about 0.1% to about 99.9% (w/w).

97. (Previously Presented) The method of claim 96, wherein the concentration of the active agent is from about 5% to about 70% (w/w).

98. (Previously Presented) The method of claim 97, wherein the concentration of the active agent is from about 15% to about 40% (w/w).

99. (Previously Presented) The method of claim 87, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 99.9% to about 0.1% (w/w).

100. (Previously Presented) The method of claim 99, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 95% to about 30% (w/w).

101. (Previously Presented) The method of claim 100, wherein the concentration of the pharmaceutically acceptable water-soluble or water-dispersible excipient is from about 85% to about 60% (w/w).

102. (Previously Presented) The method of claim 87, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of a sugar, a sugar alcohol, a starch, a natural gum, a natural polymer, a synthetic derivative of a natural polymer, a synthetic polymer, and mixtures thereof.

103. (Previously Presented) The method of claim 102, wherein said at least one pharmaceutically acceptable water-soluble or water-dispersible excipient is selected from the group consisting of lactose, glucose, mannose, mannitol, sorbitol, xylitol, erythritol, lactitol, maltitol, corn starch, potato starch, maize starch, gelatin, carrageenin, acacia, xanthan gum, an alginate, dextran, maltodextran, polyethylene glycol, polyvinylpyrrolidone, polyvinylalcohol, polyoxyethylene copolymers, polyoxypropylene copolymers, polyethyleneoxide, and a mixture thereof.

104. (Previously Presented) The method of claim 102, wherein said excipient is selected from the group consisting of a direct compression material and a non-direct compression material.

105. (Previously Presented) The method of claim 104, wherein said excipient is selected from the group consisting of a spray-dried mannitol and spray-dried lactose.

106. (Previously Presented) The method of claim 87, wherein the poorly soluble active agent is in the form of crystalline particles, semi-crystalline particles, or amorphous particles.

107.-109. (Cancelled)

110. (Withdrawn) The method of claim 87, wherein the active agent is nifedipine.

111. (Withdrawn) The method of claim 87, wherein the active agent is glipizide.